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10/636,081	08/06/2003	Pramod K. Gupta	24866A	9824

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EXAMINER	
PARA, ANNETTE H	

ART UNIT	PAPER NUMBER
1661	

NOTIFICATION DATE	DELIVERY MODE
12/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@weyerhaeuser.com

Office Action Summary	Application No.	Applicant(s)	
	10/636,081	GUPTA ET AL.	
	Examiner	Art Unit	
	ANNETTE H. PARA	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15-19,21,23 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-19, 21, 23,and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-13, 15-19, 21, 23 and 24 are rejected. Claims 14, 20 and 22 are cancelled.

The Rejection of Claims 1-13, 15-18, 21, 23 and 24 under 35 U.S.C. § 112, First Paragraph (New Matter) has been withdrawn in view of Applicant's amendment of the claims.

The Rejection of Claims 1-13, 15-18, 21, 23 and 24 under 35 U.S.C. § 112, second paragraph has been withdrawn in view of Applicant's amendment of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 15-19, 21, 23 and 24 remain rejected under 35 U.S.C.102 (b) as being clearly anticipated by Pullman et al. (US 5,294,549 published on March, 15 1994).

The claims are drawn to a method for producing conifer somatic embryos by cultivating pre-cotyledonary cells in a medium comprising nutrient wherein the osmolality is from 180 mM/Kg to 400 mM/Kg then transferring them to a medium comprising abscisic acid, gibberellin and activated charcoal as an absorbent for a period of .5 week to 5 weeks. And finally, transferring the pre-cotyledonary somatic embryos to a development medium for a period from 9 to 14 weeks to produce cotyledonary somatic embryos.

Pullman et al teach a method of cultivating conifer pro-cotyledonary somatic embryos in a maintenance medium comprising nutrients that sustain the embryos. The maintenance medium has an osmolality of 170mM/Kg to about 240 mM/Kg (column 15, lines 1-3). The pro-cotyledonary are then transferred to a singulation medium comprising gibberellin and/or abscisic acid at concentrations of 0.05 and 15 mg/L (col. 13, lines 40-60) and

comprising also activated charcoal (col. 13, lines 50-54), for at least 3 weeks (col. 15, lines 23-26). This medium has a reduced osmotic level compared to the one of the maintenance medium, thus less than 170 mM/Kg (column 15, lines 13-14). Finally, the pro-cotyledonary embryos are transferred to a development medium wherein the osmolality is above about 400 mM/Kg (col. 15, line 60). Pullman et al. also teach the use of activated charcoal at a concentration of 2.5g/L (Table 2). Further Pullman et al. teach media with a pH of 5.7 (Table 1). Fifty percent and 75% of the embryos population taught by Pullman et al. is inherently at the same developmental stage, absent evidence to the contrary. Pullman et al. teach that this method can be used for many species including loblolly pine (col. 7, lines 50-60). Pullman et al. is silent in the time frame period claimed in step (c) and but since Pullman et al. follow the same steps than those claimed by the instant Application, the time frame characteristic of 9 to 14 weeks is enough for inherent anticipation, absent evidence to the contrary.

Comment

No Claims are allowed

Response to argument received on August 8, 2008

Applicant's arguments have been fully considered but they are not persuasive.

Applicants argue that: Claim 1 (Currently amended) A method for producing a synchronized population of conifer somatic embryos, the method comprising:
(a) cultivating pre-cotyledonary conifer embryogenic cells in, or on
a maintenance medium comprising nutrients that sustain the embryos and one or
more agents for adjusting the osmolality of the medium to a desired range;
(b) cultivating pre-cotyledonary conifer embryogenic cells from step (a) for a period from 0.5 weeks to 5 weeks in, or on, a synchronization medium that comprises an absorbent composition and at least one synchronization agent selected from the group consisting of abscisic acid and a gibberellin, wherein the absorbent composition and the at least one synchronization agent are present at a concentration effective to produce a synchronized population of pre-cotyledonary conifer somatic embryos wherein at least 50% of the embryos in the synchronized population are at the same developmental stage; and
(c) transferring the synchronized population of pre-cotyledonary conifer somatic embryos from step (b) to a development medium and incubating the embryos for a period from 9 to 14 weeks to produce a synchronized population of cotyledonary conifer somatic embryos.
Support for this amendment is found in the Specification as filed, for example at page 2, lines 26-27; page 7, lines 28-30; page 8, lines 1-13; page 9, lines 5-29; page l 1, lines 7-14; and Examples 1 and 2.
It is respectfiflly submitted that Pullman et al. does not anticipate the claimed invention as amended. In order to anticipate, the reference must disclose, either expressly or inherently, each and every element of the claim. M.P.E.P. 2131.
The present invention is generally directed to culturing conifer embryos in synchronization medium containing activated charcoal and at least one of abscisic acid and a gibberellin prior to incubation in development media. As

described in the instant specification, cleavage polyembryony (embryonal suspensor mass proliferation) continues in cultures after plating onto development medium, and new embryos are beginning to develop even after eight weeks of culture on development medium. Due to this continuing cleavage, embryos are not uniform in stage, shape, size or quality within a single plate. This lack of uniformity detrimentally affects the efficiency of somatic cloning of conifers. The present invention addresses the problem of unsynchronized development of conifer embryogenic cells, including ESMs, by culturing the embryonic cells in, or on, a synchronization medium that causes the majority of embryos in a population of conifer somatic embryos to progress through successive developmental stages together to yield a synchronized population of mature conifer somatic embryos that can be germinated to form conifer plants. As described in Examples 1 and 2 of the instant specification, the present inventors discovered through experimentation that culturing conifer embryos in synchronization medium containing activated charcoal and at least one of abscisic acid and a gibberellin prior to incubation in development media inhibited precocious embryo development and greening, while promoting singulation and synchronization of the cultures, resulting in embryos very uniform in size in comparison to control cultures. See specification at page 19, lines 19-31.
Pullman et al. does not remotely teach, suggest, or provide any motivation to produce a synchronized population of cotyledonary conifer somatic embryos as claimed. Therefore, it is noted that the incubation in synchronization media for 0.5 to 5 weeks prior to incubation in a development media as recited in Claim 1 step (b) is an important distinction between the Pullman et al. reference and the present invention.
In contrast to the present invention, Pullman et al. is directed to the use of gibberellin along with abscisic acid in the development medium during somatic embryogenesis. See Pullman et al., Col. 10, lines 15-17. As shown in Table 2 of Pullman et al., the multistage culturing process of Pullman et al. for somatic embryogenesis in Douglas fir includes Stage I: initiation; Stage II: Maintenance 1; Stage III: Maintenance 2; Stage IV: Singulation; Stage V: Development; and Stage VI: Germination. As further shown in Table 2, at Stage V: Development does the medium include activated charcoal and at least one of abscisic acid or gibberellins. In the Advisory Action mailed on June 12, 2007, with reference to Example 9, the Examiner asserted that "Pullman et al. teach column 22, Table 9, media 1 and 2 initial medium then transferred to a medium comprising ABA and charcoal (medium 1) or comprising ABA, GA and charcoal (medium 2)." However, applicants wish to point out, contrary to the Examiner's assertion, that column 22, Table 9 clearly states that "no transfers made" for media 1 and media 2. As further described in Examples 8 and 9 of Pullman et al., Norway Spruce late stage proembryos referenced in Table 9 (including those incubated in media 1 and media 2) were plated directly from a maintenance medium onto solid development media containing various concentrations of ABA and GA. Therefore, based on the description in Example 8 and 9 of Pullman et al., the embryos incubated in media 1 and media 2 were plated directly from a maintenance media onto the respective development media and incubated on the same development media during the entire development time, with no pre-development synchronization step. In this regard, the Examiner has further asserted that "similar methods are presumed to inherently possess the same properties." However, contrary to the Examiner's assertion, it is further noted that the methods described in the Pullman et al. reference do not inherently possess the same properties of the claimed invention. With regard to inherency, as stated in M.P.E.P. Section 2112, "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Exparte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).
As described in Example 2 of the instant specification, it was experimentally demonstrated that in the absence of the step of culturing in a synchronization medium, the control cultures grown in maintenance medium and directly transferred to development media (similar to the method in Pulman et al.) were cleaving, growing and forming embryo suspensor masses, with embryos seen in many different stages.

These arguments are not found persuasive because Pullman et al. teach culturing of proembryos in a maintenance medium then transferring the late proembryos in a singulation medium comprising active gibberellins and abscisic acid and finally transferring these proembryos to an embryo development medium (column 15, lines 5-35). Pullman et al. state that adding the singulation step is beneficial for improvement of proembryos quality (column 8, lines 5-14). Pullman et al. also teach that "*for virtually all coniferous species a supply of exogenous absic acid is a*

useful hormone in the development from proembryos to cotyledonary embryos...this was always used in combination with an absorbent such as activated charcoal."(column 9, lines 49-55). Pullman et al. then add that the addition of the combination of Gibbereline and Absisic acid reduces tendency to precocious germination. The singulation step taught by Pullman et al. is identical to the synchronization step as claimed. Thus, the method taught by Pullman et al. is identical to the present method as it comprises every step of the claimed method, and is presumed to inherently possess the same properties. The method described in example 1 is for Douglas-fir embryos but earlier Pullman et al. state: *It appears now that the inclusion of between 0.05 and 15 mg/L preferably about .1-5 mg/L of selected active gibberellins and abscisic acid in the late proembryo development media is also beneficial for improvement of proembryo quality...These may then transferred to an embryo development medium...*(column 8, lines 4-14). Pullman et al also clearly state: *species other than Douglas-fir can be advantageously cultured by beginning early cotyledonary embryo development in a series of media similar to those used for Douglas-fir singulation.*(column 8, lines 49-52). Pullman et al. clearly anticipate the claimed application as amended.

Applicants further argue that As mentioned above, Example 2 of the instant specification demonstrates that control cultures grown in maintenance medium and transferred directly to development media containing 25mg/L ABA and 0.1% activated charcoal (see TABLE 2) did not result in a synchronized population and instead were observed to be cleaving, growing and forming embryo suspensor masses, with embryos seen in many different developmental stages. See specification at page 19, lines 1-5. Therefore, because the media 1 conditions of Pullman et al. are very similar to that of the control culture in Example 2, a similar result would be expected, with no synchronization.
In sharp contrast, as further described in Example 2 of the instant specification, embryos that were cultured in synchronization media prior to incubation in development media "were very uniform in size compared to the control embryos." Specification at page 19, lines 25-26. The study described in Example 2 concluded that "uniform growth of early stage embryos before transfer to development medium can be achieved by pre-treating cultures in a synchronization medium containing activated charcoal and at least one of abscisic acid and a gibberelin. This treatment synchronized cotyledonary embryo development and maturation." Page 19, lines 27-31.
Because Pullman et al. does not disclose or suggest culturing conifer embryos in a synchronization medium prior to development as claimed, the cited reference fails to teach or suggest all the elements of the claimed invention and therefore does not anticipate or render obvious the method of the claimed invention.
Thus, it is submitted that Pullman et al. does not anticipate nor render obvious the claimed invention, as amended. Removal of this ground of rejection is respectfully requested.

These arguments are not found persuasive because Pullman et al. teach culturing conifer proembryos in a maintenance medium then transferring these proembryos to a singulation medium comprising abscisic acid, activated charcoal and gibbereline (synchronization medium as claimed) and finally transferring them to a development medium (column 15, lines 5-35). Pullman et al. is silent about the uniformity in size of the embryos

obtained but a reference which is silent about a claimed invention's feature is inherently anticipatory if the missing feature is necessarily present in that which is described in the reference. *In re Oelrich,* 212 USPQ 323 (CCPA 1981).

Response to Arguments received on September 24, 2008

Applicant's arguments have been fully considered but they are not persuasive.

Applicants argue that they respectfully traverse this ground of rejection for the following reasons.
As an initial matter, it is noted that the Pullman et al. reference was previously cited by the Examiner in the Office Action dated June 12, 2007, which was previously addressed in applicants' response filed on August 8, 2007. It is further noted that in the subsequent Office Action mailed on November 14, 2007, the only grounds of rejection were based on 35 U.S.C. § 112, with no mention of either the Pullman et al. reference or the arguments presented by applicants regarding the prior rejection based on the Pullman et al. reference. Therefore, it appeared that the Examiner had withdrawn the previous rejection based on the Pullman et al. reference. As stated in the M.P.E.P § 707.07, in taking up an amended application for action, the Examiner should note in every letter all the requirements outstanding against the application and every point in the prior action of an Examiner which is still applicable must be repeated or referred to, to prevent the implied waiver of the requirement. As further stated in M.P.E.P § 707.07, "where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." Therefore, for at least the reasons described in applicants' response to the Office Action mailed on August 8, 2007, applicants maintain the view that the claimed invention is novel and non-obvious in view of Pullman et al.
With regard to the Examiner's assertion in the instant Office Action that Pullman et al. discloses transferring embryos to a medium comprising gibberellin and/or abscisic acid at concentrations of 0.05 and 15 g/L (with reference to Col. 13, lines 40-60) and comprising also activated charcoal (with reference to Col. 13, lines 50-54), for at least 3 weeks (with reference to Col. 15, lines 23-26), it is noted that the passages now relied on by the Examiner describe the singulation stage used to culture Douglas-fir somatic embryos. There is no teaching or suggestion in Pullman et al. to culture pine embryos in the multistep process as recited in Claim 1, with a first incubation on maintenance media, followed by incubation in synchronization media, followed by incubation in development media.
As described in Pullman et al., "Douglas-fir generally requires an intermediate step between the late proembryo growth stage and the final cotyledonary embryo development stage which is not necessary for other species. The proembryos tend to form in tight clumps or clusters which must first be singulated before going to the development stage." Pullman et al. at Col. 8, lines 18-23 (emphasis added). Consistent with this teaching regarding the need for singulation in Douglas-fir culture, Examples 1, 2, 3, 4, 5, 6, and 7 of Pullman et al., all directed to growth of Douglas-fir embryos, all include the step of singulation (e.g., see Col. 14, line 4, to Col. 20, line 40). In contrast, the methods for culturing embryos from Norway spruce taught in Pullman et al. involved plating directly from a maintenance medium onto solid development medium in Examples 8, and 9, with no singulation step (see Pullman et al. at Col. 20, line 41, to Col. 23, line 30).
Moreover, Pullman et al., does not remotely teach, suggest, or provide any motivation to produce a synchronized population of cotyledonary pine somatic embryos as claimed.
As described in Examples 1 and 2 of the instant specification, the present inventors discovered through experimentation that culturing pine embryos in synchronization medium containing activated charcoal and at least one of abscisic acid and a gibberellin prior to incubation in development media inhibited precocious embryo development and greening, while promoting singulation and synchronization of the cultures, resulting in embryos very uniform in size in comparison to control cultures. See specification at page 19, lines 19-31.
Therefore, it is noted that the incubation of pre-cotyledonary pine embryogenic cells in synchronization media for 0.5 to 5 weeks prior to incubation in a development media as recited in Claim 1 step (b) is an important distinction between the Pullman et al. reference and the present invention.
In this regard, the Examiner has further asserted that "similar methods are presumed to inherently possess the same

properties." However, contrary to the Examiner's assertion, it is further noted that the methods described in the Pullman et al. reference do not inherently possess the same properties of the claimed invention. With regard to inherency, as stated in M.P.E.P. § 2112, "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Exparte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

It is noted that the media used in the treatment of the control Loblolly pine embryogenic cell culture in Example 2 of the instant specification is very similar to the media used in the treatment of the Norway spruce embryos using media As mentioned above, Example 2 of the instant specification demonstrates that control Loblolly pine embryogenic cell cultures grown in maintenance medium and transferred directly to development media containing 25 mg/L ABA and 0.1% activated charcoal (see TABLE 2) did not result in a synchronized population and instead were observed to be cleaving, growing, and forming embryo suspensor masses, with embryos seen in many different developmental stages. See specification at page 19, lines 1-5. Therefore, because the media 1 conditions of Pullman et al. are very similar to that of the control culture in Example 2, a similar result would be expected, with no synchronization.

In sharp contrast, as further described in Example 2 of the instant specification, Loblolly pine embryogenic cell cultures that were cultured in synchronization media prior to incubation in development media "were very uniform in size compared to the control embryos." Specification at page 19, lines 25-26. The study described in Example 2 concluded that "uniform growth of early stage embryos before transfer to development medium can be achieved by pre-treating cultures in a synchronization medium containing activated charcoal and at least one of abscisic acid and a gibberellin. This treatment synchronized cotyledonary embryo development and maturation." Page 19, lines 27-31. Because Pullman et al. does not disclose or suggest culturing pine embryos in a synchronization medium prior to development as claimed, the cited reference fails to teach or suggest all the elements of the claimed invention and therefore does not anticipate or render obvious the method of the claimed invention. Accordingly, removal of this ground of rejection is respectfully requested.

These arguments are not found persuasive because Pullman et al. teach culturing of proembryos in a maintenance medium then transferring the late proembryos in a singulation medium (synchronization medium) comprising active gibberellins, abscisic acid and charcoal, and finally transferring these proembryos to an embryo development medium (column 15, lines 5-35). Adding the singulation step is described by Pullman et al. as being beneficial for improvement of proembryos quality (column 8, lines 5-14). Pullman et al. also teach that "*for virtually all coniferous species a supply of exogenous absic acid is a useful hormone in the development from proembryos to cotyledonary embryos...this was always used in combination with an absorbent such as activated charcoal.*"(column 9, lines 49-55). Pullman et al. then add that the addition of the combination of Gibbereline and Absisic acid reduces tendency to precocious germination. The method taught by Pullman et al. is identical to the present method because Pullman et al. teach every steps of the claimed method, thus is presumed to inherently possess the same properties. The method described in example 1 is for Douglas-fir embryos but earlier Pullman et al. state: *It appears now that the inclusion of between 0.05 and 15 mg/L preferably about .1-5 mg/L of selected active gibberellins and abscisic acid in the late proembryo development media is also beneficial for improvement of*

proembryo quality...These may then transferred to an embryo development medium...(column 8, lines 4-14). Pullman et al also clearly state: *species other than Douglas-fir can be advantageously cultured by beginning early cotyledonary embryo development in a series of media similar to those used for Douglas-fir singulation.*(column 8, lines 49-52). Pullman et al. clearly anticipate the claimed application as amended.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette H. Para whose telephone number is (571) 272-0982. The examiner can normally be reached Monday through Thursday from 5:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975. The fax number for the organization where the application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either the Private

PAIR or the Public PAIR. Status information for unpublished applications is available through the Private PAIR only.

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/Annette H Para/
Primary Examiner